O 3 2006 THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Pal Maliga, et al.

Serial No. : 10/737,251

Filing Date : December 15, 2003

Examiner : Anne R. Kubelik

Group Art Unit : 1638

Entitled : "Plastid rRNA Operon

Promoter Elements for Construction of Chimeric Promoters for Transgene

Expression"

\_\_\_\_\_

07/06/2006 HDESTA1 00000052 10737251

01 FC:1806 180.00 OP

Suite 2400

1601 Market Street Philadelphia, PA 19103

(215) 563-4100 (telephone)

(215) 563-4044 (facsimile)

Our File No. 1594-RUT.03-083US

Certificate of Mailing Under 37 C.F.R. §1.8(a):

I hereby certify that this correspondence is being deposited on Juc 71, 2006 with the United States Postal Service as first-class mail in an envelope properly addressed to the Mail Stop: AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Robert C. Netter, Jr., Ph.D.

Mail Stop: AMENDMENT Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

## <u>UNDER 37 C.F.R. §1.97</u>

Dear Sir:

In compliance with the duty of disclosure set forth in 37 C.F.R. § 1.56, Applicants are submitting herewith 1 sheet of Form PTO/SB/08A and 4 sheets of Form PTO/SB/08B and copies of the

non-patent literature references listed thereon. This Information Disclosure Statement is being filed after receipt of an Official Action on the merits but before the mailing of a Final Official Action or a Notice of Allowance. Accordingly, the fee required under 37 C.F.R. 1.97(c) is enclosed.

This submission is not an admission that the references listed on the attached Form PTO/SB/08A and Form PTO/SB/08B constitute prior art against the claims of this application.

The Examiner is respectfully requested to confirm receipt and consideration of the cited reference by initialing and returning a copy of the attached Form PTO/SB/08A and PTO/SB/08B in accordance with MPEP §609.

In the event that any additional fee is required in connection with this submission and not enclosed, the Commissioner is authorized to charge Deposit Account No. 04-1406 of the undersigned attorneys. A duplicate copy of this sheet is enclosed.

Early and favorable consideration of this application is respectfully requested.

Respectfully submitted,
DANN, DORFMAN, HERRELL AND SKILLMAN
A Professional Corporation
Agent for Applicants

Robert C. Netter, Jr., Ph.D.

Registration No. 56,422

RCN:LCF

Enclosures - Form PTO/SB/08A and Form PTO/SB/08B - Copy of non-patent literature references

PTO/SB/08A (07-05)

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

o.s. Patent and Trademark Office; U.s. DEPARTMENT OF COMMERCE
of the Paperwood Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Under the Paperwo	Reduction	Acf 8/1995,
Substitute for form	n PTO	MARK STO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 5

Complete if Known				
Application Number	10/737,251			
Filing Date	December 15, 2003			
First Named Inventor	Maliga et al.			
Art Unit	1638			
Examiner Name	Anne R. Kubelik			
Attorney Docket Number	1594-RUT.03-083US			

			U. S. PATEN	DOCUMENTS		
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2 (f known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Pages, Columns, Line Applicant of Cited Document Relevant Passages or Figures Appea		
	A1	<sup>US-</sup> 6,987,215	01-17-2006	Maliga		
-	A2	<sup>US-</sup> 6,624,296	09-23-2003	Maliga		
	А3	<sup>US-</sup> 6,472,586	10-29-2002	Maliga		
	A4	<sup>US-</sup> 6,388,168	05-14-2002	Maliga		
	A5	<sup>US-</sup> 6,376,744	04-23-2002	Maliga		
	A6	<sup>US-</sup> 6,297,054	10-02-2001	Maliga		
	A7	<sup>US-</sup> 5,545,818	08-13-1996	McBride		
	A8	<sup>US-</sup> 5,451,513	09-19-1995	Maliga		
		US-				
		US-				
		US-				
		ÚS-				
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				
<del>-</del>	1	US-				

		FOREIG	GN PATENT DOCU	MENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T <sup>6</sup>

Examiner	Date	
Signature	Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO		Complete if Known			
Substitu	10 10 10 11 144 3/1 10			Application Number	10/737,251
INF	ORMATION	DIS	CLOSURE	Filing Date	December 15, 2003
STA	TEMENT E	BY A	PPLICANT	First Named Inventor	Maliga et al.
	//		annanana)	Art Unit	1638
	(Use as many she	ets as n	ecessary)	Examiner Name	Anne R. Kubelik
Sheet	2	of	5	Attorney Docket Number	1594-RUT.03-083US

	-	NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>			
TOZAWA, Y., et al., "Nuclear encoding of a plastid sigma factor in rice and its tissue- and light-dependent expression," Nuc. Acids Res., 26:415-419, (1998)						
TAN, S., et al., "Characterization of two cholorplast RNA polymerase sigma factors from Zea mays: photoregulation," Proc. Natl. Acad. Sci. USA, 96:5316-5321, (1999).						
SVAB, Z., et al., "High-frequency plastid transformation in tobacco by selection for a chimeric aadA gene," Proc. Natl. Acad. Sci. USA, 90:913-917, (1993).						
SUN, E., et al., "In vitro analysis of the pea chloroplast 16S rRNA gene promoter," Mol. and Cell. Biol., 9:5650-5659, (1989).						
STRITTMATTER, G., et al., "Identification of an rRNA operon promoter from Zea mays chloroplasts which excludes the proximal," EMBO J., 4:599-604, (1985).						
STAUB, J.M., et al., "Accumulation of D1 polypeptide in tobacco plastids is regulated via the untranslated region," EMBO J., 12:601-606, (1993).						
***	<b>C</b> 7	SRIRAMAN, P., et al., "The phage-type PclpP-53 plastid promoter comprises sequences downstream of the transcription initiation site," Nuc. Acids Res., 26:4874-4879, (1998).				
	SRIRAMAN, P., et al., "Transcription from heterologous rRNA operon promoters in chloroplasts reveals requirement for specific," Plant Physiol., 117:1495-1499, (1998).					
	SHIINA, T., et al., "rbcL transcript levels in tobacco plastids are independent or light: reduced dark transcription rate is," Plant Cell, 10:1713-1722, (1998).					
	C10	ROSS, W., et al., "E. coli Fis protein activates ribosomal RNA transcription in vitro and in vivo," EMBO J., 9:3733-3742, (1990).				

Examiner	Date
Signature	Considered

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Panerwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<u>Un</u> Subatitu	Substitute for form 1449/PTO		Complete if Known		
Substitu	ite for form 1449/FTO			Application Number	10/737,251
INF	ORMATION	I DIS	CLOSURE	Filing Date	December 15, 2003
STA	TEMENT E	3Y A	PPLICANT	First Named Inventor	Maliga et al.
	##	4		Art Unit	1638
	(Use as many sheets as necessary)			Examiner Name	Anne R. Kubelik
Sheet	3	of	5	Attorney Docket Number	1594-RUT.03-083US

		NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No.1 Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.							
	OROZCO, E.M., et al., "An in vitro system for accurate transcription initiation of chloroplast protein genes," Nuc. Acids Res., 13:1283-1302, (1985).							
	C12	LIERE, K., et al., "In vitro characterization of the tobacco rpoB promoter reveals a core sequence motif conserved between phage-type plastid," EMBO J., 18:249-257, (1999).						
	LAHIRI, S.D., et al., "Complementary expression of two plastid-localized sigma-like factors in maize," Plant Physiol., 123:883-894, (2000).							
KIM, M., et al., "Detailed architechture of the barley chloroplast psbD-psbC blue light-responsive promoter," J. Biol. Chem., 274:4684-4692, (1999).								
	KIM, M., et al., "Identification of a sequence-specific DNA binding factor requried for transcription of the barley chloroplast," Plant Cell, 7:1445-1457, (1995).							
	C16 KESTERMANN, M., et al., "Sequence and expression characteristics of a nuclear-encoded chloroplast sigma factor," Nuc. Acids Res., 26:2747-2753, (1998).							
-	C17	JOLLY, S.O., et al., "Preferential transcription of cloned maize chloroplast DNA sequences by maize chloroplast RNA polymerase," Proc. Natl. Acad. Sci. USA, 77:822-826, (1980)						
	ISONO, K., et al., "Leaf-specifically expressed genes for polypeptides destined for chloroplasts with domains of," Proc. Natl. Acad. Sci. USA, 94:14948-14953, (1997).							
	C19 IRATNI, R., et al., "Organ-specific transcription of the rrn operon," J. Biol. Chem., 272:13676-13682, (1997).							
	C20	HIRVONEN, C., et al., "Contributions of UP elements and the transcription factor FIS to expression from the seven rrn P1 promoters," J. Bact. 183:6305-6314, (2001).						

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
d to a collection of information unless it contains a valid OMB control number.

Substitu	Substitute for form 1449/PTO			Complete if Known		
Jupstitu	Re 101 101111 1443/F 10			Application Number	10/737,251	
INF	ORMATION	DIS	CLOSURE	Filing Date	December 15, 2003	
STA	TEMENT E	BY A	PPLICANT	First Named Inventor	Maliga et al.	
	///	4		Art Unit	1638	
	(Use as many sheets as necessary)			Examiner Name	Anne R. Kubelik	
Sheet	4	of	5	Attorney Docket Number	1594-RUT.03-083US	

		NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*				
	C21	HAKIMI, M-A., et al., "Evolutionary conservation of C-terminal domains of primary sigma 70-type," J. Biol. Chem., 275:9215-9221, (2000).		
	C22	GRUISSEM, W., et al., "Analysis of promoter regions for the spinach chloroplast rbcL, atpB and psbA genes," EMBO J., 4:3375-3383, (1985).		
	C23	EISERMANN, A., et al., "In vitro transcription and DNA binding characteristics of chloroplast and etioplast extracts from mustard," EMBO J., 9:3961-3987, (1990).		
	C24	DUBELL, A.N., et al., "Differential transcription of pea chloroplast genes during light-induced leaf development," Plant Physiol., 109:105-112, (1995).		
	C25	CHUN, L., et al., "Phytochrome A mediates blue light and UV-A-dependent chloroplast gene transcription in green leaves," Plant Physiol., 125:1957-1966, (2001).		
	C26	CHAN, C.L., et al., "The anti-initial transcribed sequence, a portable sequence that impedes promoter escape," J. Biol. Chem., 276:38201-38209, (2001).		
	C27	BLIGNY, M., et al., "Regulation of plastid rDNA transcription by interaction of CDF2 with two different RNA polymerases," EMBO J., 19:1851-1860, (2000).		
	C28	BAUMGARTNER, B.J., et al., "Plastid genes encoding the transcription/translation apparatus are differentially," Plant Physiol., 101:781-791, (1993).		
	C29	ALLISON, L.A., et al., "Deletion of rpoB reveals a second distinct transcription system in plastids of higher plants," EMBO J., 15:2802-2809, (1996).		
	C30	ALLISON, L.A., et al., "Light-responsive and transcription-enhancing elements regulate the plastid psbD core promoter," EMBO J., 14:3721-3730, (1995).		

Examiner	Date		
Signature	Considered	 	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Inder the Panerwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449/PTO				Complete if Known		
Substitu	10 10111 1443/1 10			Application Number	10/737,251	
INF	ORMATION	DIS	CLOSURE	Filing Date	December 15, 2003	
STA	STATEMENT BY APPLICANT			First Named Inventor	Maliga et al.	
(Use as many sheets as necessary)				Art Unit	1638	
			ecessary)	Examiner Name	Anne R. Kubelik	
Sheet	4	of	5	Attorney Docket Number	1594-RUT.03-083US	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C31	AIYAR, S.E., et al., "Upstream A-tracts increase bacterial promoter activity through interactions with," Proc. Natl. Acad. Sci. USA, 95:14652-14657, (1998).	
	C32	MANNA, F., et al., "A tRNA gene mapping within the chloroplast rDNA cluster is differentially expressed during the development," Nuc. Acids Res., 22:1712-1718, (1994).	

Examiner	Date	
Signature	 Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.